VIII. 510(K) SUMMARY

A. Sponsor/Submitter:

Perclose
400 Saginaw Drive
Redwood City, CA 94063
Tel: (650) 474-3000
Fax: (650) 474-3020

B. Contact Person:

Daun S. Putnam
Regulatory Affairs Coordinator
(650) 474-3135

C. Date of Submission: June 16, 2000

D. Trade (Brand) Name: SuperCross™ Catheter

E. Common Name: Percutaneous Catheter

F. Classification: Class II

G. Classification Name: Percutaneous Catheter, 21 CFR Part 870.1250

H. Product Code: 74DQY

I. Predicate Devices:

1. Cordis Vista Brite Tip™ guiding catheter, cleared July 14, 1997 (K971572).
2. Scimed® 7 French Wiseguide™ guide catheter, cleared February 19, 1998 (K974684).

J. Intended Use:

The SuperCross catheter is intended to negotiate stenotic or tortuous lesions of the iliac, femoral, popliteal, tibial, and renal arteries in order to facilitate placement and positioning of other catheters. The SuperCross catheter is not intended for use in the coronary or cerebral vasculature. The SuperCross catheter is not intended for use to dilate lesions.

K. Device Description:

The SuperCross catheter features a 7 French compatibile stainless steel braided polyimide shaft which is attached to a steerable dilator at the distal end of the device. The proximal end of the shaft is connected to a handle and rotating hemostasis valve assembly. The dilator consists of two halves. One half articulates about a hinge pin and the other half is fixed to the shaft. The dilator is actuated by wire connected to a lever and it may be rotated 360 degrees with the control of the shaft. A guide wire lumen through the device accepts a non-polymer coated 0.018" guide wire.

L. Summary of Substantial Equivalence:

Perclose has submitted information on the indication for use, design, principle of operation, biocompatibility and performance characteristics to establish that the SuperCross catheter is substantially equivalent to currently marketed predicate devices.

The SuperCross catheter has essentially the same intended use as the predicate devices. Questions regarding the effects of any different technological characteristics of the SuperCross catheter have been answered through accepted scientific methods. These methods assessed new characteristics with regard to safety, functionality and reliability under simulated conditions of use. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use. Non-clinical testing such as strength and force testing were conducted. Animal testing was performed to simulate clinical conditions with no adverse effects noted. Clinical evidence further supported the safety and performance of the Supercross catheter when used as intended.

In conclusion, the SuperCross catheter has been shown to be substantially equivalent to the Class II predicates on which the device is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2001

Ms. Daun S. Putnam
Regulatory Affairs Coordinator
Perclose, Inc
400 Saginaw Drive
Redwood City, CA 94063

Re: K001856
Trade Name: SuperCross™ Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: December 22, 2000
Received: December 26, 2000

Dear Ms. Putnam:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K001856

Device Name: SuperCross™ Catheter

Indications for Use: The SuperCross catheter is intended to negotiate stenotic or tortuous lesions of the iliac, femoral, popliteal, tibial, and renal arteries in order to facilitate placement and positioning of other catheters. The SuperCross catheter is not intended for use in the coronary or cerebral vasculature. The SuperCross catheter is not intended for use to dilate lesions.

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Division of Cardiovascular & Respiratory Devices
510(k) Number K001856